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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,386	04/01/2008	Nikolaos Berntenis	21796	6749
	7590 09/14/201 ¹ LA ROCHE INC.	EXAMINER		
	DEPARTMENT	EWOLDT, GERALD R		
340 KINGSLAND STREET NUTLEY, NJ 07110			ART UNIT	PAPER NUMBER
			1644	
			MAIL DATE	DELIVERY MODE
			09/14/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

1) Responsive to communication(s) filed on <i>QT July 2010</i> . 2a This action is FINAL. 2b This action is non-final. 3 Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4 Claim(s) <i>1-15.17,18,23,25 and 31</i> is/are pending in the application. 4a) Of the above claim(s) <i>3-13.15,17,18,23,25 and 31</i> is/are withdrawn from consideration. 5 Claim(s)							
Examiner Art Unit 1644 1644 1644 1644 1644 1644 1644 1644 1644 1644 1644 1644 1644 1644 1645 1644 1644 1644 1644 1644 1644 1644 1645		Application No.	Applicant(s)				
C.R. Ewoldt, Ph.D. 1644		10/567,386	BERNTENIS ET AL.				
The MALING DATE of this communication appears on the cover sheet with the correspondence address — Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensives for time may be available under the proximace of 37 CFR 1.1680, in no event bowers, may a right be limity filled. If NO period for right is appelled above, the maximum statutory, princed will apply and will expire SIX (8) MONTH'S from the mailing date of this communication. Period will apply and will expire SIX (8) MONTH'S from the mailing date of this communication, even if timely filled, may reduce any visitor to prize the maximum statutory. Six (8) MONTH'S from the mailing date of this communication, even if timely filled, may reduce any visitor to prize the mailing date of the communication, even if timely filled, may reduce any visitor to prize the mailing date of this communication, even if timely filled, may reduce any visitor to prize the mailing date of this communication, even if timely filled, may reduce any visitor to prize the mailing date of this communication, even if timely filled, may reduce any visitor to prize the mailing date of this communication, even if timely filled, may reduce any visitor to prize the maximum and the mailing date of this communication, even if timely filled, may reduce any visitor to prize the maximum and timely state to the prize the maximum and timely filled. The prize the maximum and timely filled, may reduce any visitor and timely filled, may reduce any visitor and timely filled. 1)	Office Action Summary	Examiner	Art Unit				
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DETAILED ACTION

1. Applicant's election of Group I, the peptide of SEQ ID NO:49, with traverse, submitted 7/07/10, is acknowledged.

Applicant cites MPEP chapter 800 and argues a lack of burden in the search of all of the Groups.

Applicant is advised that MPEP chapter 800 does not apply to the instant National Stage Application filed under 35 USC 371. MPEP chapter 1800 applies to the instant application and Lack of Unity has been properly established there under.

Applicant further argues that the cited reference, WO 93/18153 teaches only a sequence that is "apparently similar", "but not identical to", the sequence of SEQ ID NO:109.

Applicant has provided no evidence that the cited sequence in WO 93/18153 does not comprise that of SEQ ID NO:109 in the instant application, and it is further noted that Applicant did not traverse this finding in response to the International Preliminary Report on Patentability.

Also note that even under the rules of MPEP chapter 1800 multiple products, e.g., different unrelated peptides, are not considered to comprise a single invention.

It is noted that the elected invention, a peptide comprising the amino acid sequence of SEQ ID NO:49, is a fragment of the protein gamma-interferon-inducible lysosomal thiol reductase (GILT). Applicant is advised that peptides claimed in this application that consist of additional fragments of GILT will be considered to be non-elected species rather than separate inventions. Applicant is requested to identify any such fragments should they exist.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 3-13, 15, 17, 23, 25, and 31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected inventions/species. Note that Applicant incorrectly identified Claim 23 as reading on the elected invention.

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Claims 1, 2, and 14 are being acted upon.

- 3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. All sequences in the specification and figures must be identified by SEQ ID NO:. See, for example, the sequences at pages 9, 39, 41, 42, etc. of the specification.
- 4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as anticipated by Arunachalam et al. (2000).

Arunachalam et al. teaches a peptide comprising the amino acid sequence of SEQ ID NO:49 (see particularly Figure 1A.).

The reference clearly anticipates the claimed invention.

- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 7. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Arunachalam et al. (2000) in view of Jüsten et al. (2000) and Godkins et al. (2001).

Arunachalam et al. has been discussed above.

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The reference teaching differs from the claimed invention only in that it does not teach a peptide comprising the amino acid sequence of SEQ ID NO:49 further comprising an MHC Class II molecule.

Jüsten et al. (2000) teaches that in their search for genes and gene products that might be involved in the pathogenesis of rheumatoid arthritis (RA) they found that GILT was overexpressed in RA patients (see particularly, page 167, column 2) and noted that "it is striking" that GILT colocalizes in APCs with intracellular MHC Class II molecules (see particularly, page 170, column 1).

Godkins et al. (2001) teaches the routine purification of MHC Class II antigenic peptides comprising the lysing of MHC Class II expressing cells, the isolation of MHC Class II/antigenic peptide complexes, and the subsequent purification of the peptides from said complexes (see particularly, page 6721, Purification of naturally produced HLA class II molecules and Pool Sequencing).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to provide a complex of the peptide comprising the amino acid sequence of SEQ ID NO:49 further comprising an MHC Class II molecule for the identification and study of the peptide and its possible role in the pathogenesis of RA given the teachings of Jüsten et al., that "it is striking" that GILT colocalizes in APCs with intracellular MHC Class II molecules, employing the routine method of Godkins et al. The ordinarily skilled artisan would have been interested in the peptide of SEQ ID NO:49 as a candidate MHC class II antigenic peptide particularly in light of the teachings of Jüsten et al.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ram Shukla, can be reached on (571) 272-0841.

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10. Please Note: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.

/G.R. Ewoldt/
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Primary Examiner
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